

Office Action Summary

Application No.
09/524,027

Applicant(s)
Burrell et al.

Examiner
Kim M. Lewis

Art Unit
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/12/00, 6/16/00 and 10/23/00
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar 13, 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Detailed Action*

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DETAILED ACTION

Oath/Declaration

1. The declaration filed 6/12/00 has been received and made of record in the application file wrapper.

Response to Amendment

2. The preliminary amendment filed on 10/19/200 has been received. Claims 1, 3, and 21 have been amended. Claims 25 and 26 have been added. The applicant should note that the amendment to claims 4 and 22 have not been entered since a claim must depend from a previous claim. The applicant should note, however, that in order to advance prosecution, the examiner has examined the claims as amended.

Information Disclosure Statement

3. The information disclosure statement papers filed 6/16/00 have been received, which papers have been made of record in the application file wrapper.

Drawings

4. The drawings are objected to because of the following:

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Fig. 4 is colored black so as to prevent the examiner from seeing the described slit (page 6, lines 27-28);

Lower surface "36" is not in Fig. 2 (page 8, line 4); and

Reference character "40" is associated with dressing "22" not "20" (page 6, lines 7-8).

The applicant is advised to peruse the specification and drawings for other such inconsistencies. Correction is required.

Specification

5. The disclosure is objected to because of the following informalities:

Page 2, line 9, "device" should read --devices--;

Page 2, line 9, "a" should read --an--;

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-22, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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As regards claims 3-22, 25 and 26, "The dressing or method" is indefinite in that the examiner is unclear as to whether the applicant intends for the claim to depend from a method claim or an apparatus claim.

As regards claims 21 and 26, "the **optional** third layer"(**emphasis added**) lacks antecedent basis.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-22, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/41095 (Burrell et al.) in view of U.S. Patent No. 3,918,446 ("Buttaravoli").

As regards claim 1, Burrell et al. disclose substantially all features of the claimed invention including a multi-layer laminated wound dressing (Fig. 2). The dressing includes first (12), second (14) and third (16) layers, wherein the first and third layers are constructed from perforated, non-adherent materials which carry an anti-microbial coating on one or more surfaces (page 12, lines 28-29). The second layer is sandwiched between the first and third layers and is formed from an absorbent material. Burrell et al. fail to teach top and bottom dressings and a slit in the bottom dressing.

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Buttaravoli discloses a securement device for an intravenous catheter (transcutaneous medical device) and its tubing. Buttaravoli's device comprises an upper pad and a bottom pad having at least one slit. It would have been obvious to one having ordinary skill in the art to modify Burrell et al. to include an additional dressing having a slit therein in order to provide the user with a securement device for an intravenous catheter having anti-microbial effects.

As regards claim 2, the modified device of Burrell et al. is placed on a user in a manner similar to that of Buttaravoli (col. 4, line 41- col. 6, line 13).

As regards claim 3, col. 6, lines 14-19 of Buttaravoli discloses an integrally hinged dressing. See also Fig. 11.

As regards claim 4, note the abstract and page 9, line 22-page 11, line 10 and page 12, line 28-29, which discloses that the anti-microbial material is deposited on one or more surfaces of the substrate.

As regards claim 5, as can be seen from Fig. 9 of Buttaravoli, fold line (66) is parallel to slit (76).

As regards claim 6, note the abstract of Burrell et al., which discloses the dressings is made from multi-layered, laminated dressing materials.

As regards claim 7, note Fig. 2 and page 16, lines 5-21, which discloses the dressing is constructed from first, second and third layers. When modified to include two dressings as disclosed in Buttaravoli, both the top and bottom dressings will include three layers.

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As regards claim 8, note the abstract, which discloses the anti-microbial material is on the first and third layers.

As regards claim 9, as can be seen from Figs. 5, 6, 7, 8 and 12, Buttaravoli discloses the medical device protrudes at least 5 mm. It may then be inferred that the modified dressing would also provide coverage of the portion of the medical device protruding from the skin of at least 5 mm.

As regards claims 10 and 11, note page 3, lines 9-19 of Burrell et al.

As regards claims 12, 13 and 14, Burrell et al. disclose the presently claimed metals in the base layer and the top layer on page 3, lines 9-32.

As regards claim 15, note claim 6, which discloses co-, sequentially or reactively depositing the anti-microbial metal by vapor deposition along with the other claimed features.

As regards claim 16, note claim 7 and 19 of Burrell et al.

As regards claim 17, note claim 21 of Burrell et al.

As regards claim 19, note claim 22 of Burrell et al.

As regards claim 20, note claim 24 of Burrell et al.

As regards claim 21, the presently claimed material for the first and third layers is disclosed on page 16, lines 23-28 and page 17, lines 27-29 of Burrell et al.

As regards claim 22, the presently claimed material for the second layer is disclosed on page 16, lines 18-19 and page 17, lines 13-22 of Burrell et al..

As regards claim 25, note the rejection of claim 3, *supra*.

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As regards claim 26, note the rejection of claim 21, *supra*.

10. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. in view of Buttaravoli, as applied to claims 2 and 22, respectively, and in further view of U.S. Patent No. 4,738,257 ("Meyer et al.") .

As regards claims 23 and 24, both Burrell et al. and Buttaravoli fail to teach an occlusive or semi-occlusive layer which maintains the dressing in moist condition. However, Meyer et al. teach a dressing fixed in place with an occlusive film layer in order to maintain the dressing in a moist condition. It would have been obvious to one having ordinary skill in the art to provide the modified device of Burrell et al. with an occlusive film layer in order to maintain moisture in the dressings, as suggested by Meyer et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (703) 308-1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss, can be reached on (703) 308-2702. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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kml
November 13, 2001


KIM M. LEWIS
PRIMARY EXAMINER